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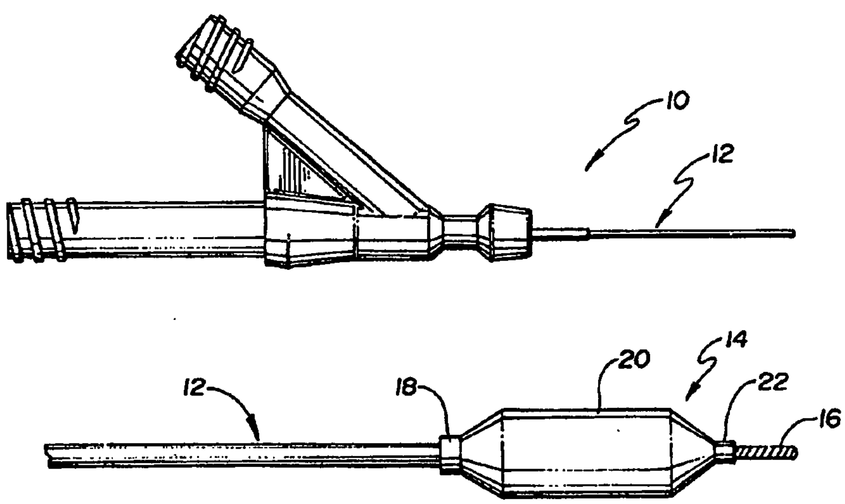

(57) Abstract

The present invention discloses the incorporation of thermoplastic polyimide into various parts of balloon catheters such as catheter shafts and balloons. Such catheter construction may be integral or unitary in which the shaft or a portion thereof and balloon are manufactured as a single unit or the construction may be comprised of a separate shaft to which a balloon is attached, as by adhesive or other bonding.

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Termoplastic polyimide Balloon catheter

Background of the Invention

This invention relates to dilation balloon catheters, particularly those used in angioplasty. More specifically, it relates to the balloons on such catheters and to some extent to the catheter shaft as well. Angioplasty relates to opening of stenoses in the vascular system usually by means of a catheter having a balloon at its distal end. Such catheters may be single or multiple lumen, may be over-the-wire or non-over-the-wire. Very similar catheters may be used for placing stents. All such catheters are referred to herein collectively as "balloon catheters". The invention described herein could also be utilized in the production and manufacture of guide catheters or infusion catheters.

It is possible to make balloons from a variety of materials that are generally of the thermoplastic polymeric type. Such materials may include: polyethylenes and ionomers, ethylene-butylene-styrene block copolymers blended with low molecular weight polystyrene and, optionally, polypropylene, and similar compositions substituting butadiene or isoprene in place of the ethylene and butylene; poly(vinyl chloride); polyurethanes; copolyesters; thermoplastic rubbers; siliconepolycarbonate copolymers; and ethylene-vinyl acetate copolymers.

One material of choice for such catheters has been thermoset polyimide, primarily because of its high strength and flexibility in small diameter with very thin walls. Being thermoset, the polyimide used heretofore has involved complicated manufacturing procedures due to the fact that it is insoluble and "intractable" i.e., not meltable. For example, in forming catheter shafts, it has been necessary to build up the shaft with multiple layers of polyimide on a substrate which is subsequently dissolved away. This has also been necessary in making the catheter balloon in which multiple layers of

thermoset polyimide were layered onto a form, of glass for example, which was later etched away leaving a polyimide balloon.

This type of polyimide is a heterochain polymer typically made of two base monomers, a diamine and a dianhydride (e.g. para-aminoaniline and pyromellitic dianhydride). Such polyimide is typically formed by two step reaction like the following example. First, a polyamide is formed from the monomers. The reaction proceeds at about 25° C. and the product is soluble and stable in very polar solvents. Second, the polyamide is condensed to polyimide at about 120° C. Further description of polyimides and their preparation can be found in Androva et al. *Polyimide, A New Class of Heat-Resistant Polymers*, pp. 4-13 (1969).

As already indicated other plastics have been used in catheter construction for shafts and balloons in which the plastic has been of the thermoplastic type. For example, polyethylene terephthalate (PET) has been used to make the balloons. Thermoplastic materials lend themselves to simpler manufacturing techniques, such as extrusion in forming shafts and blow molding in forming the balloons than do the aforementioned thermoset polyimide materials due to the fact that they are soluble and meltable. However, the art has failed to recognize that thermoplastic polyimide is available for balloon catheter construction.

Although many of the procedures employing balloon catheters are still in the experimental stage in the United States, there is a considerable amount of art available on the formation and use of balloon catheters. Illustrations of such art are: U.S. Patent Nos. 4,952,357 to Euteneuer; 4,413,989 and 4,456,000 to Schjeldahl et al. and 4,490,421 as well as Reissue Patent Nos. 32,983 and 33,561 to Levy.

The Euteneuer patent relates to the prior art polyimide catheter/balloon construction. The Schjeldahl patents, incorporated herein by reference, pertain to catheter assemblies or attachments. These patents

disclose expanders (balloons) formed from a thin, flexible, inelastic, high tensile strength, biaxially oriented, synthetic plastic material. The Levy patents, which issued several years after the Schjeldahl patents, sought to provide balloons exhibiting physical properties superior to those exhibited by prior art balloons. The specific qualities Levy emphasized were toughness, flexibility and tensile strength. Levy teaches that a high tensile strength balloon can only be formed from a high intrinsic viscosity polymer, specifically, high molecular weight polyethylene terephthalate.

High tensile strengths are important in angioplasty balloons because they allow for the use of high pressure in a balloon having a relatively small wall thickness. High pressure is often needed to treat some forms of stenosis. Small wall thicknesses enable the deflated balloon to remain narrow, making it easier to advance the balloon through the arterial system.

Summary of the Invention

It is the primary purpose of this invention to apply thermoplastic polyimide to the art of balloon catheter construction, i.e., to catheter shafts and balloons. It is another purpose of this invention to apply thermoplastic polyimide to the art of guide catheter construction and infusion catheter construction. Such catheter construction may be either integral or unitary in which the shaft or a portion thereof and balloon are manufactured as a single unit or the construction may be comprised of a separate shaft to which a balloon is attached, as by adhesive or other bonding.

Brief Description of the Drawings

A detailed description of the invention is hereafter described with specific reference being made to the drawings in which:

FIG. 1 is a schematic; somewhat idealized view of a balloon catheter using thermoplastic polyimide according to the invention in both shaft

and balloon portions.

FIG. 2 is a partial sectional view of the distal portion of the catheter shown comprising a longitudinal cross-sectional view of the balloon of FIG. 1.

FIGS. 3 and 4 are enlarged cross-sectional views of portions of a wall of a balloon having a plurality of layers forming the wall i.e., a composite of thermoset and thermoplastic polyimide.

FIG. 5 is a front view, with portions broken away, showing a shaft of the catheter of FIG. 1 which is a polyimide shaft with braided reinforcement;

FIG. 6 is a cross-sectional view of the shaft of FIG. 5 taken on line 6-6 of FIG. 5;

FIG. 7A is a cross-sectional view of a shaft according to the present invention, wherein the shaft has a reinforcement at its innermost diameter and a polyimide coating over the reinforcement structure;

FIG. 7B is a cross-sectional view of a shaft according to the present invention comprising a thermoplastic polyimide material surrounding a reinforcement material;

FIG. 8 is a cross-sectional view of a shaft according to the present invention, wherein the shaft has a reinforcement material embedded in the outermost diameter of the polyimide substrate;

FIG. 9 is a cross-sectional view of a shaft according to the present invention, wherein the shaft has a reinforcement material at its innermost diameter with polyimide coating the reinforcement structure;

FIG. 10 is a cross-sectional view of a shaft according to the present invention, wherein the shaft is formed from a blend of polyimide and a reinforcing material;

FIG. 11 is a cross-sectional view of a shaft according to the present invention, wherein the shaft is formed of a fluoropolymer at the inner

diameter, a layer of polyimide surrounding the fluoropolymer layer and a reinforcement material bonded to or embedded in the polyimide layer;

FIG. 12 is a cross-sectional view of a shaft according to the present invention, wherein said shaft is formed of a polyimide inner layer, an intermediate reinforcing material and an outer polyimide layer;

FIG. 13 is a cross-sectional view of a shaft according to the present invention, wherein said shaft is formed from a coextruded shaft having a polyimide/liquid crystal polymer blend surrounding its inner diameter and polyimide surrounding its outer diameter;

FIG. 14 is a cross-sectional view of a shaft according to the present invention, wherein said shaft is formed from a coextruded shaft having a polyimide/liquid crystal polymer blend surrounding its outer diameter and polyimide surrounding its inner diameter;

FIG. 15 is a cross-sectional view of a shaft according to the present invention having an inner layer of polytetrafluoroethylene surrounded by an outer layer comprising thermoplastic polyimide or a thermoplastic polyimide blend;

FIG. 16 is a cross-sectional view of a shaft according to the present invention comprising inner and outer layers of polyimide surrounding an intermediate layer comprising a blend; and

FIG. 17 is a partial sectional view of the shaft of a catheter according to the present invention.

Description of the Preferred Embodiments

The invention lies in a high strength, thin walled, balloon, and in some instances the catheter shaft or portions thereof, formed from a thermoplastic polyimide. The invention also encompasses the process for manufacturing such a balloon and/or catheter shaft, and could also be utilized in the production and manufacture of guide catheters or infusion catheters.

A balloon of this invention is preferably obtained by extruding thermoplastic polyimide tubing and then expanding the extruded tubing axially and radially. Any conventional extruder may be employed to perform the extrusion process.

Figure 1 shows a schematic view of a balloon catheter, shown generally at 10. Catheter 10 has an elongated flexible shaft 12 which according to the invention, may at least in part, be comprised of thermoplastic polyimide. That is, the entire length thereof may consist of thermoplastic polyimide or a longitudinal section or sections thereof may consist of thermoplastic polyimide or it may be entirely of another material with only the balloon being of thermoplastic polyimide. Since it is thermoplastic at least in part, shaft 12 may be formed by tubular extrusion as is the case of the techniques known in this art for extruding other thermoplastic materials such as the PET aforementioned and as already described hereinabove. In a preferred embodiment of the present invention, thermoplastic polyimide is present in both shaft and balloon portions.

Mounted at the distal end of catheter 10, shown in the lower portion of Figure 1, which is enlarged to show detail, shaft 12 is fitted with an inflatable thin wall balloon generally designated at 14 (shown inflated). Depending on the particular construction of the catheter, the distal tip 16 may be the distal end of a guide wire as shown or it may be the distal end of the catheter per se.

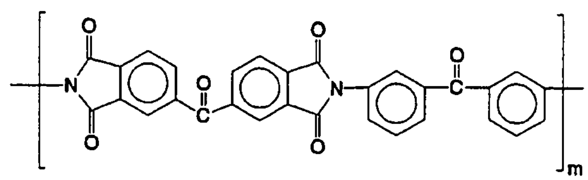
Shaft 12 has at least one lumen (not shown) extending from its proximal to its distal end. Depending on its construction, multiple lumens may be provided. In any case, at least an inflation lumen extends through shaft 12 for selective inflation and deflation of balloon 14. Any or all of the lumens may be made from thermoplastic polyimide.

Balloon 14 is a thin wall thermoplastic polyimide balloon formed in the art known manner by blow molding as described above. This technique

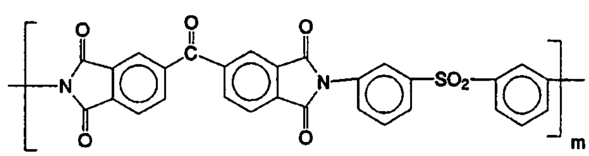
is also discussed in the aforementioned United States Patent 4,490,421 for forming PET balloons. As seen in Figure 1, a balloon in one embodiment comprises a proximal waist portion 18 bonded to the distal end of shaft 12, an intermediate inflatable body portion 20 of a larger diameter than waist 18, and a smaller distal end portion 22.

Thermoplastic polyimide is a linear aromatic polyimide first developed by NASA and described in *NASA Conf. Pub. #2334 (1984)* at pp. 337-355, entitled *THERMOPLASTIC/MELT-PROCESSABLE POLYIMIDES*, authored by T.L. St. Clair and H.D. Burks.

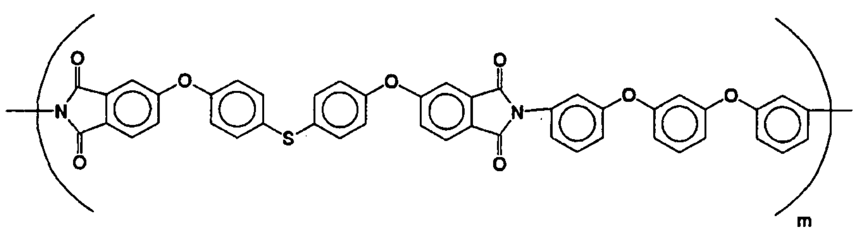
The structural formula is shown as follows:



Also shown in that reference is a polyimide sulfone:



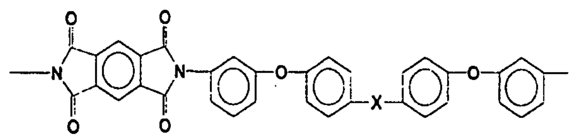
and is a polyphenylene ethersulfideimide:



Any of the above examples of polyimides may be used according to this invention.

One such thermoplastic polyimide is available commercially under the tradename AURUM® from Mitsui Toatsu Chemicals, Inc., of Tokyo,

Japan. It is the thermoplastic polyimide resin which is described in detail in United States Patent 5,069,848 issued December 3, 1991 and European Patent Application 0,391,633 and is shown as having the following structural formula:



wherein X is a single bond or a hexafluoroisopropylidene group, the foregoing references being incorporated herein in their entirety by reference.

Thermoplastic polyimide, as used herein, refers to any polyimide polymer which is reprocessable, i.e., the polymer can be heated to a temperature at which it is soft enough to be reprocessed or extruded but at which temperature it will not decompose to any appreciable degree. Thermoset polyimide, by contrast cannot be reprocessed or reextruded after it has been formed due to the fact that the material crosslinks or forms chemical bonds as the material is being formed.

Applicants have found that the thermoplastic polyimide, when formed into a balloon by stretching and blowing, exhibits amorphous or only slightly crystallized (up to 10%) behavior.

The extruded thermoplastic polyimide tubing for use in making balloons according to this invention can be formed with wall thicknesses as low as on the order of .001 to .015 inches which can readily be used for forming balloons by blow molding with wall thicknesses on the order of .0003" to .003" inches.

The present invention has several important advantages. First, thermoplastic polyimide balloons offer thin walls but have a high burst pressure, up to 16 atmospheres and even higher, up to 20 atmospheres. Thermoplastic polyimide shafts are readily extrudable. Thermoplastic

polyimide decomposes at a temperature range above about 400°-410°C. The softening temperature of thermoplastic polyimide is about 320°-380°C, and the melting temperature is about 340-410°C. The physical properties of thermoplastic polyimide offer the opportunity of secondary forming operations. For example, the material as extruded tubing can be reheated and a balloon can be blown out of it. Thermoplastic can be remelted. Scrap can be ground up and run through an extruder again. Thermoset polyimide cross links upon curing, which precludes the possibility of remelting for reuse or recycling.

There is a tendency for the fracture mode upon failure of prior art thermoset polyimide balloons to be more of a catastrophic fracture rather than the preferred longitudinal burst mode of thermoplastic polyimide balloons of the invention. For this reason, an alternate embodiment of the invention with respect to balloon construction may comprise a multiple layer balloon of the type shown in Figures 2 - 4. This balloon generally designated 30 is comprised of a blow molded balloon of thermoplastic polyimide having a deposited outer layer 34 of prior art thermoset polyimide, polyamide, or any other material laid down in the known manner on the inflated thermoplastic polyimide 32 of the balloon. Such construction provides a balloon having predominantly longitudinal burst characteristics. This embodiment also offers one the opportunity of tailoring the compliance characteristics of the balloon by selectively altering the number, arrangement and thickness of these layers in a variety of configurations. Moreover, the thermoplastic polyimide balloons of the invention may have no outer layer at all or they may carry a single outer layer or multiple outer layers (full or partial) of extruded thermoplastic polyimide or other polymer materials for layer 34.

In manufacturing the balloons of the invention, techniques and tools utilized in the prior art for thermoplastic balloons are readily adaptable.

Considering all of the foregoing, thermoplastic polyimide balloons may be readily manufactured which have, for example, diameters of

about 1.5 - 25mm, lengths of about 5 - 200mm, wall thicknesses of about 0.0003 - 0.003 inches and to any of the typical ranges for balloon dimensions and strengths as typically utilized in the medical industry heretofore. The minimum length is from about 5mm to about 10mm, and the most preferred length is about 20mm in length.

EXTRUSION OF THERMOPLASTIC POLYIMIDE

The drying and extrusion equipment must be thoroughly clean and dry to reduce possibility of material contamination. It is important to sufficiently pre-dry the resin prior to extrusion to prevent creation of surface defects caused by moisture. The resin can be dried by a desiccant type hot air dryer using -40F dew point air in a plenum style hopper. The moisture content of the polyimide is controlled to less than 100ppm by varying both drying temperature and time. Polyimide resin dried at a temperature of 180C in excess of 10 hours provides desired moisture levels. An extruder with a length to diameter ratio of about 25:1 and a minimum of three barrel temperature control zones with additional heater control zones for adapter, head and die is adequate. Temperature controllers are proportioning type in order to maintain tight temperature control and a homogeneous melt. Both barrel and screw of the extruder are made of conventional bimetallic material that is surface hardened and chrome plated. Conventional nitride metals tend to degrade by oxidation which causes the generation of black rust at high temperatures. A preferred screw for the extruder is a Barrior design having a length to diameter ratio of from 18 to 28:1 and a compression ratio of 2.7:1 with a zone distribution of about 25% feed, 46% compression, and 30% metering. General purpose screw with 2.5 to 3.5:1 compression ratios and a relatively constant transition from feed to metering zone have also worked effectively. Breaker plate, adapter, head, and tooling are hard chrome plated and streamlined, i.e., gradual transitions, rounded edges and minimal obstructions. Screen packs with a micron rating of 40 to 80 mesh having

stainless steel gauge construction are generally sufficient to generate adequate back pressure. Die and tip cross-sectional area drawdown ratios (which is the area defined by the die and mandrel divided by the cross-sectional area of the extruded tubing) can range from 3 to 30:1, and die land lengths range from 10 to 60 times the desired product wall thickness. Sizing can be accomplished by free extrusion methods, maintaining constant nitrogen pressure inside the tubing while being quenched in a conventional water bath at ambient temperatures.

The pre-dried thermoplastic polyimide pellets are preferably delivered to the feed throat of an extruder from a plenum style/hopper, and conveyed forward through several heating zones by rotating the extruder screw. Melt temperature of the polyimide is maintained from 340C to 410C by the various zone temperature controllers, and by shear generated from the action of a 3/4 or 1 1/4 inch diameter screw rotating at speeds ranging from 2 to 50 RPM. The material then passes through a screen pack, breaker plate, adapter, tooling head, and extrusion tooling where it is shaped to form the desired product. Optimally, the residence time in the extruder is kept to a minimum. Once the material exits the tooling in its desired form, it needs to be cooled. One way to perform the cooling process is to pass the extruded tubing from the extruder, through an air gap between tooling and quench tank ranging from 0.25 to 25 inches, and into a water bath maintained at a temperature ranging from 40F to 120F. A haul-off may be used to pull the tube from the cooled end through the quench tank. Thereafter, the product is spooled or cut to length as desired.

BALLOON FORMING WITH THERMOPLASTIC POLYIMIDE

Some minimal initial orientation of polyimide material is accomplished as the material is drawn down during extrusion. This orientation process is typically known as machine orientation and is formed in the

direction of extrusion operation. A small amount of additional longitudinal orientation occurs during balloon formation. This additional orientation is the result of the material elongation at blow molding temperatures, and is caused by the weight of the balloon mold stretching the tubing downward at a ratio of 1.1 to 3:1 at molding temperatures ranging from 230C to 330C. The preferred longitudinal stretch time at molding temperatures is from 8 to 10 minutes. Method improvements to optimize stretching and heating will probably reduce stretch times. Once the optimum longitudinal stretch is achieved, the tubing is expanded radially using internal pressures ranging from 3 to 100 psig. However, the preferred pressure is 20 to 50 psig. This is accomplished by providing a pressurized fluid or gas, preferably nitrogen gas, to the inner lumen of tubing. Tubing extends outside both ends of the mold, one end is clamped off such that no gas can flow through it, and the opposite end is pressurized to form the balloon. An appropriate mold with the tubing inside, may be heated while pressure is applied. The preferred molding temperature ranges from 260C to 300C. The dimensions to which it is stretched are preferably controlled by performing the radial stretching while the tubing is in a mold having the shape of the desired balloon. Suitable molds are known in the art. The tubing subjected to specific interior pressures and exterior heat is held stationary for a period of time, preferably 4 to 6 minutes, while the balloon and waist portions yield completely and stabilize. Method improvements to optimize balloon mold heating will probably result in reduced heat soak cycles. The radial expansion, or hoop ratio (calculated by dividing the inner diameter of the balloon by the inner diameter of the extruded tubing), should be in the range of 3 to 8:1. The preferred hoop ratio is approximately 5:1. The tubing, now comprising the balloon, is next cooled. One way to cool the balloon is to remove the mold from the heat chamber and place it in a cooling bath. The cooling bath is preferably maintained at ambient temperature. The balloon may for example, remain in the cooling bath for

approximately 10 seconds. However, a chilled bath can be used to reduce the quench cycle times. Finally, the ends of the tubing extending from the mold are cut off (unless integral catheter shaft/balloon construction is intended) and the balloon is removed from the mold by removing either the distal or proximal end from the body section of the mold, then gently pulling the balloon from the remaining mold sections.

As already indicated, for any given catheter construction, the entire shaft 12 could be polyester, polyethylene, thermoset polyimide or anything else known in the art. The thermoplastic polyimide balloon would be bonded to such a shaft. On the other hand, the balloon may be integral with the shaft or a portion thereof to provide an all thermoplastic polyimide construction.

The shaft may be composed of a blend of materials. The entire shaft or a portion thereof may be coextruded. For example, a shaft may include a layer of polytetrafluoroethylene (PTFE) surrounded by thermoplastic polyimide or a blend of thermoplastic polyimide and other polymeric and/or reinforcement components. Such a blend may comprise PTFE or carbon and thermoplastic polyimide. Examples of such blends includes up to about 10% PTFE or about 15 % carbon and a balance of thermoplastic polyimide. Another blend may include liquid crystal polymer, radiopaque materials such as bismuth salts, tungsten or titanium, silver or gold (which would impart conductivity to the blend). A shaft according to the present invention may include inner and outer layers of thermoplastic polyimide surrounding an intermediate layer comprising a blend as described above.

The shaft and/or balloon may be reinforced. The reinforcement material may comprise various types of continuous or intermittent reinforcing components used in the composites of this invention. Among such suitable materials are continuous fiber or filament forms such as polyester, polyamide or carbon fiber, and further may be sphere and particulate forms such as glass.

Reinforcing material may comprise glass, carbon, ceramic, fluoropolymer, graphite, liquid crystal polymers, polyester, polyamide, stainless steel, titanium and other metals such as nitinol, or radiopaque materials (such as Bismuth or Tungsten) and the like.

The continuous reinforcement may be used in filamentary form or it may be employed in the form of a yarn or as a fabric of plain weave, satin weave, twill weave, basket weave, braid, winding or the like. The composite structure may comprise parallel aligned continuous filaments extending within or along the inner or outermost dimension of the structure, the fibers being bonded together with the above-described thermoplastic polyimide which intimately contacts substantially the whole of the surfaces of the filaments.

Figures 5 - 6 illustrate an alternative embodiment of the shaft, shown generally at 12 of Figure 5. Shaft 12 has a continuous reinforcement in the form of a tubular braid 52 formed of individual strands 50. Polyimide material 54 encases tubular braid 52 on both the inner and outer surfaces of braid 52. Braid 52 is shown centered in polyimide material 54.

Figure 7A illustrates an alternative embodiment of the shaft of the present invention, wherein shaft 12 has a reinforcement at its innermost diameter and a polyimide coating over the reinforcement structure. Although a braided reinforcement is shown, any continuous or intermittent reinforcement as described herein may be employed. For example, Figure 7B shows a thermoplastic polyimide material 54 surrounding reinforcement material 56 comprising a material such as polyester, polyamide malleable metal or plastic.

Figure 8 illustrates a further alternative embodiment of the shaft of the present invention, wherein shaft 12 has a reinforcement material 50 embedded near the outermost diameter of thermoplastic polyimide substrate 54. Again, although a braided reinforcement material is shown, any reinforcement as described herein may be employed.

Figure 9-15 illustrate still further embodiments of the shaft of the present invention. Figure 9 shows shaft 12 having reinforcement material 50 at the innermost diameter of thermoplastic polyimide material 54. Reinforcement structure 50 is coated by polyimide material 54, but is almost exposed.

Figure 10 shows a shaft formed from a blend of polyimide and a reinforcing material. The reinforcement material as shown is in discontinuous form, i.e. dispersed particulate such as glass spheres 60 embedded throughout thermoplastic polyimide material 54. Blends as described hereinabove may be employed, as may carbon fibers as also described above.

Figure 11 shows shaft 12 formed of an inner layer 62 of a fluoropolymer, a layer of polyimide material 54 surrounding inner layer 62 and a reinforcement material 50 as described hereinabove bonded to or embedded in polyimide material 54. Figure 11 is also an example of a cross section of a guide catheter according to the present invention. By varying diameter, length and flexibility of the shafts described herein, various medical devices including infusion catheters and guide catheters can be produced.

Figure 12 shows shaft 12 formed of polyimide inner layer 68, intermediate reinforcing material 70 as described hereinabove, and an outer polyimide layer 72. Figure 13 shows shaft 12 having layer 74 comprising a polyimide/liquid crystal polymer blend layer, surrounded by a layer of polyimide 76. An alternative configuration wherein polyimide/liquid crystal polymer blend layer 74' surrounds polyimide layer 76' is shown at Figure 14.

Liquid crystal polymers are known to the art. Liquid crystal polymers are rigid, rod-like macromolecules which typically contain a substantial number of polyvalent aromatic groups such as phenylene. After alignment or orientation by shear or elongational forces, the steric hindrance of molecular rotation provided by the polyvalent or other groups causes the liquid crystal polymers to retain their orientation to effect hardening. Examples of

liquid crystal polymers are VECTRA sold by Hoechst-Celanese, or HX materials sold by DuPont, XYDAR and Econol (terpolymer of hydroxybenzoic acid, biphenol and terephthalic acid) from Dartco and Sumitomo Chemical, respectively, Vecrora from Polyplastic, and Ueno (terpolymer of 2-oxy-6-naphthoic acid, biphenol, and terephthalic acid) from Ueno Seiyaku, and any other polymer material having a rod like molecule which imparts a tendency to align more readily during melt flow than flexible chain polymers.

The embodiment of shaft 12 shown at Figure 15 includes an inner layer 80 of polytetrafluoroethylene (PTFE) surrounded by an outer layer 82 of thermoplastic polyimide. Outer layer 82 may alternatively be comprised of a blend of thermoplastic polyimide and other components as described hereinabove. A still further embodiment of shaft 12 according to the present invention as shown at Figure 16 may include inner and outer layers 86,88 of thermoplastic polyimide surrounding an intermediate layer 90 comprising a blend as described above.

A still further embodiment of shaft 12 is shown at Figure 17, where a wire winding type reinforcing material 92 is used within the polyimide to reinforce polyimide material 54.

While this invention may be embodied in many different forms, there are shown in the drawings and described in detail herein specific preferred embodiments of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

This invention has been carefully described herein in order to provide those skilled in the art with the information necessary to perform the requisite process and obtain the desired product. However, it is to be understood that the invention can be carried out by different techniques and a variety of equipment. Therefore, various known modifications, both as to equipment details and operating procedures, may be incorporated without

departing from the scope of the invention itself.

This completes the description of the preferred and alternate embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

WHAT IS CLAIMED IS:

1. An improved balloon catheter comprising a shaft portion having a proximal end and a distal end, and a balloon portion located at the distal end of said shaft portion, wherein the improvement comprises one of said portions of the balloon catheter being comprised of thermoplastic polyimide.

2. The balloon catheter of claim 1 in which at least a portion of the shaft is thermoplastic polyimide.

3. The balloon catheter of claim 1 in which the balloon is comprised at least in part of thermoplastic polyimide.

4. An improved balloon catheter comprising a shaft portion having a proximal end and a distal end, and a balloon portion located at the distal end of said shaft portion, wherein the improvement comprises the balloon portion being comprised of an innermost balloon layer and at least one additional layer, and wherein at least two of said layers are comprised of polyimide, and one of said polyimide layers is comprised of thermoplastic polyimide.

5. The balloon catheter of claim 4 in which the inner most balloon layer is thermoplastic polyimide.

6. A balloon portion of a balloon catheter wherein the balloon is comprised at least in part of thermoplastic polyimide.

7. The balloon portion of claim 6 comprised of multiple layers, one of said layers being an innermost layer, wherein at least one of said layers is thermoplastic polyimide.

8. A balloon portion of a balloon catheter, said balloon portion being comprised at least in part of thermoplastic polyimide, and further comprising at least two layers, one of said layers being an innermost layer, wherein one of said layers is a thermoplastic polyimide, and the other said layer a thermoset polyimide.

9. The balloon portion of claim 8 wherein the innermost layer is thermoplastic polyimide.

10. A catheter comprising a shaft, said shaft being comprised, at least in part, of thermoplastic polyimide.

11. A balloon catheter comprised of thermoplastic polyimide, said balloon catheter further comprising

a) a shaft having a proximal end and a distal end; and

b) a balloon portion projecting from the distal end of said shaft.

12. A catheter comprising:

a) a shaft having a proximal end and a distal end; and

b) a balloon portion further comprising:

i) a proximal waist portion constructed and arranged to be bonded to the distal end of the shaft of the catheter;

ii) an intermediate body portion of larger diameter than the waist portion;

iii) and a distal end portion of a size smaller than the proximal waist portion,

said balloon portion being comprised at least in part of thermoplastic polyimide.

13. A catheter comprising:

a) a shaft having a proximal end and a distal end; and

b) a balloon portion comprised at least in part of thermoplastic polyimide, said balloon portion further comprising:

i) a proximal waist portion constructed and arranged to be bonded to the distal end of the shaft of the catheter;

ii) an intermediate inflatable body portion of larger diameter than the waist portion;

iii) and a distal end portion of a size smaller than the proximal waist portion,

said balloon portion being comprised of multiple layers, at least one of

said layers being thermoplastic polyimide.

14. The catheter of claim 12 wherein the balloon portion has a diameter of about 1.5 - 25 mm.

15. The catheter of claim 12 wherein the balloon portion has a wall thickness of about 0.0003 - 0.003 inch.

16. A balloon portion of a balloon catheter, said balloon portion being comprised at least in part of thermoplastic polyimide, and further comprising at least two layers, one of said layers being an innermost layer, wherein one of said layers is a thermoplastic polyimide, and the other said layer is a thermoset polyimide.

17. The balloon portion of claim 16 wherein the innermost layer is thermoplastic polyimide.

18. A balloon portion of a balloon catheter comprised at least in part of thermoplastic polyimide having a melting point between about 340°C - 410°C.

19. The balloon portion of claim 18 comprised of multiple layers, one of said layers being an innermost layer, wherein at least one of said layers is thermoplastic polyimide.

20. A balloon portion of a balloon catheter as in claim 19 wherein one of said layers is thermoplastic polyimide, and the other said layer is thermoset polyimide.

21. The balloon portion of claim 20 wherein the innermost layer is thermoplastic polyimide.

22. A catheter comprising a shaft, said shaft being comprised, at least in part, of thermoplastic polyimide having a melting point between about 340°C - 410°C.

23. The catheter of claim 1 wherein at least a portion of the shaft is comprised of thermoplastic polyimide coextruded with another material.

24. The balloon catheter of claim 1 wherein the shaft and balloon

are integrally formed.

25. A catheter shaft comprised at least in part of thermoplastic polyimide, said shaft further comprising a reinforcement material.

26. The shaft of claim 25 wherein the reinforcement material is a braided reinforcement.

27. The shaft of claim 25 wherein the reinforcement is located near an outer diameter of the shaft.

28. The shaft of claim 25 wherein the reinforcement is located near an inner diameter of the shaft.

29. The shaft of claim 25 wherein the reinforcement material is a fiber.

30. The shaft of claim 25 wherein the reinforcement material is blended with thermoplastic polyimide.

31. The shaft of claim 25 wherein the reinforcement material is in a spherical form.

32. The shaft of claim 25 having an inner diameter covered with a fluoropolymer, and wherein the reinforcement material is located in the polyimide material.

Fig. 1

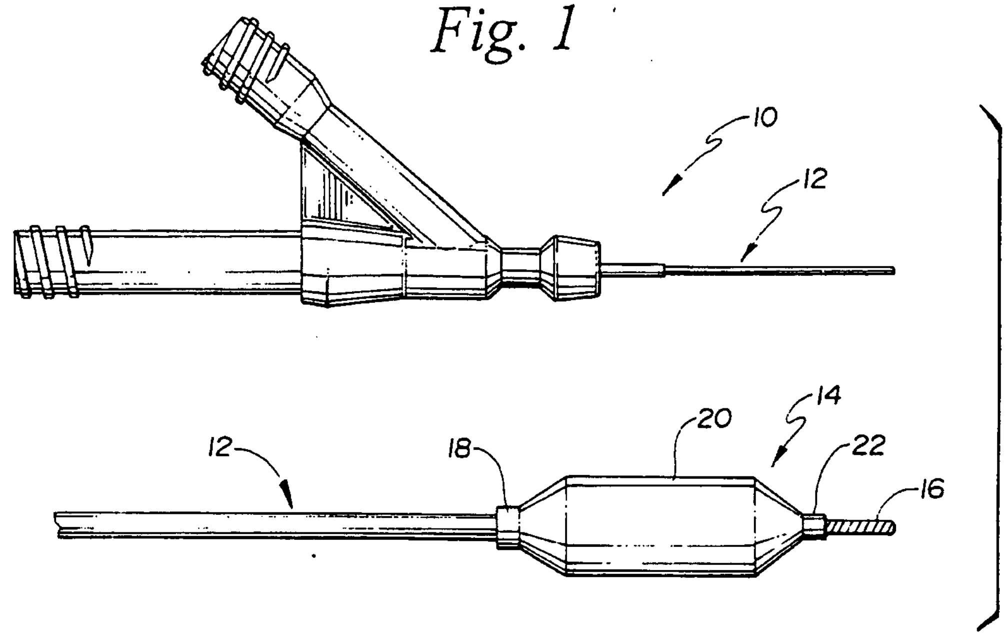


Fig. 2

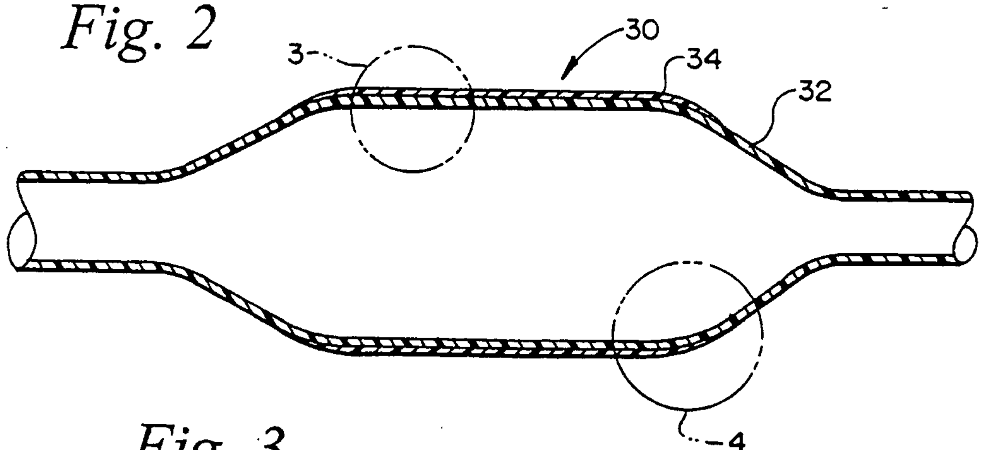


Fig. 3

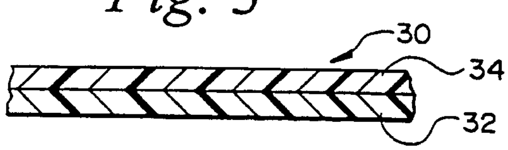


Fig. 4

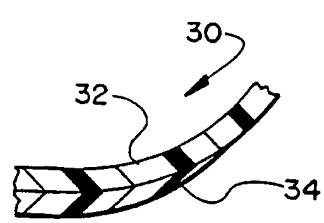


Fig. 5

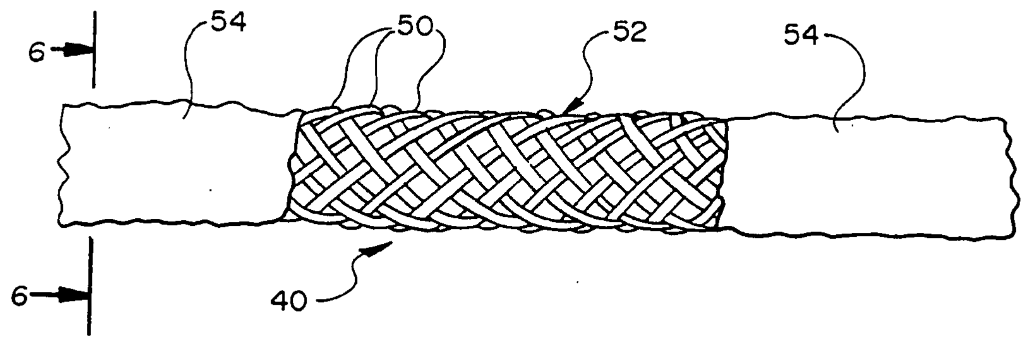


Fig. 6

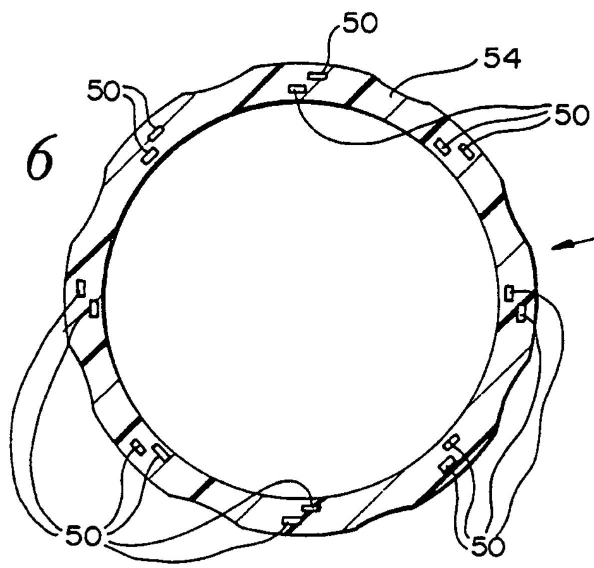


Fig. 7a

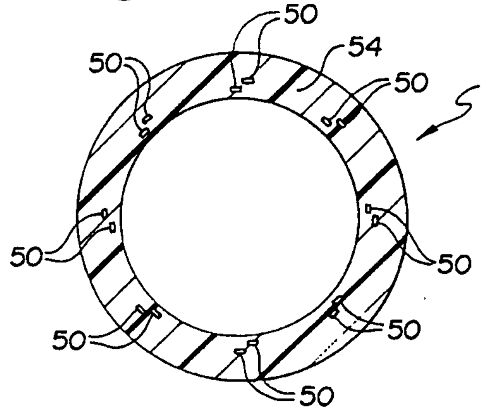


Fig. 7b

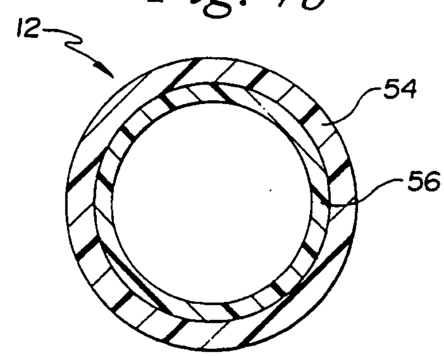


Fig. 8

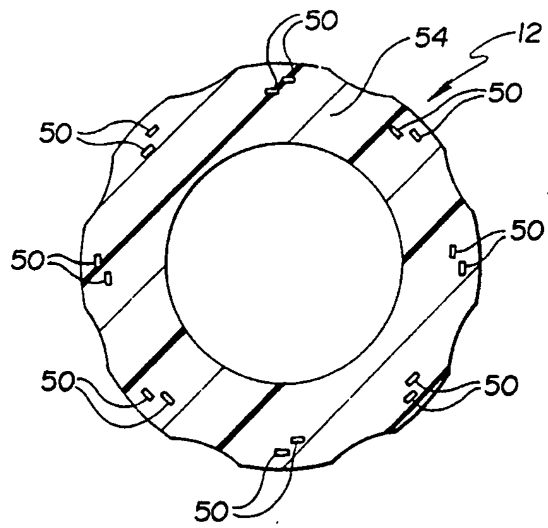


Fig. 9

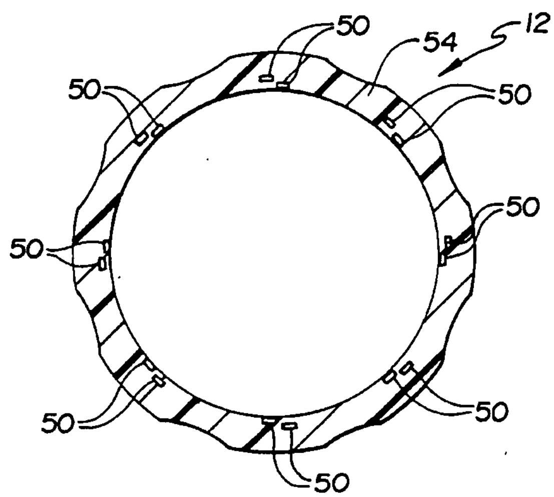


Fig. 10

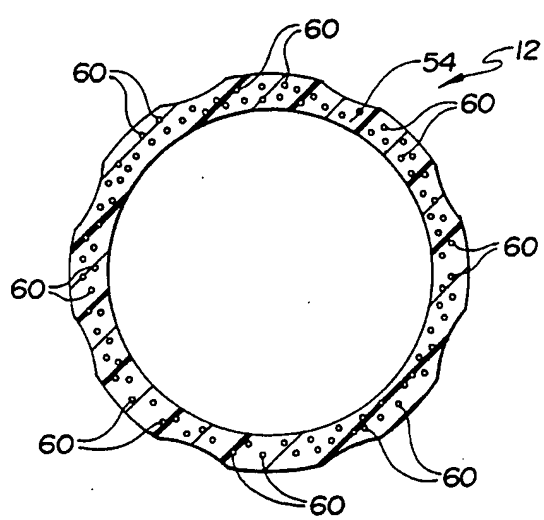


Fig. 11

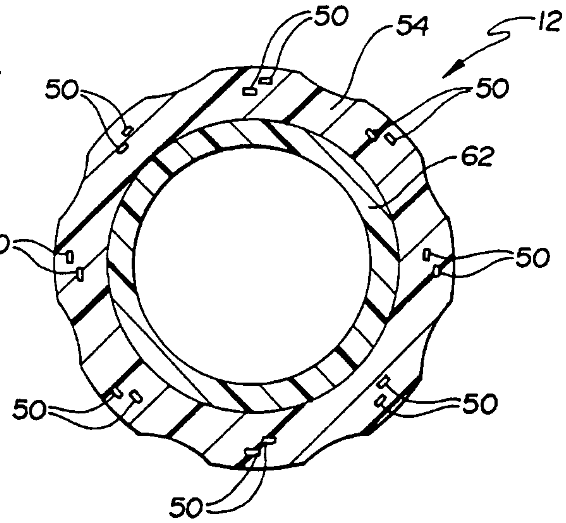


Fig. 12

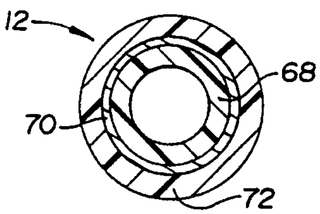


Fig. 13

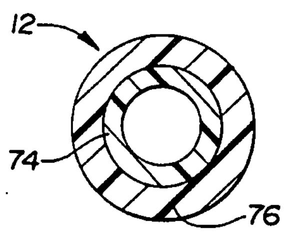


Fig. 14

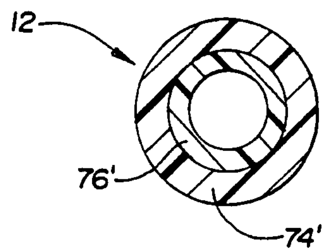


Fig. 15

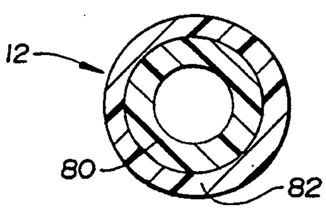


Fig. 16

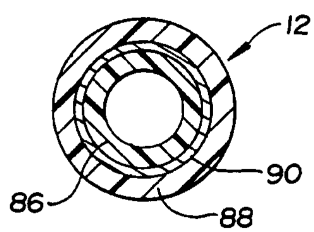
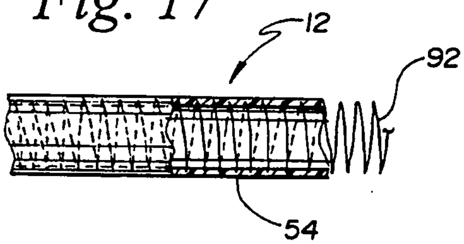


Fig. 17



PCT

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A3

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(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: RAU, Bruce, H. [US/US]; 14186 Grover Avenue N.W., Clearwater, MN 55320 (US). SHOEMAKER, Susan, M. [US/US]; 11106 - 190th Avenue N.W., Elk River, MN 55330 (US). BUSCEMI, Paul, J. [US/US]; 2310 Tamarack Drive, Long Lake, MN 55356 (US).

(74) Agents: BRENNAN, Leoniede, M. et al.; Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402 (US).

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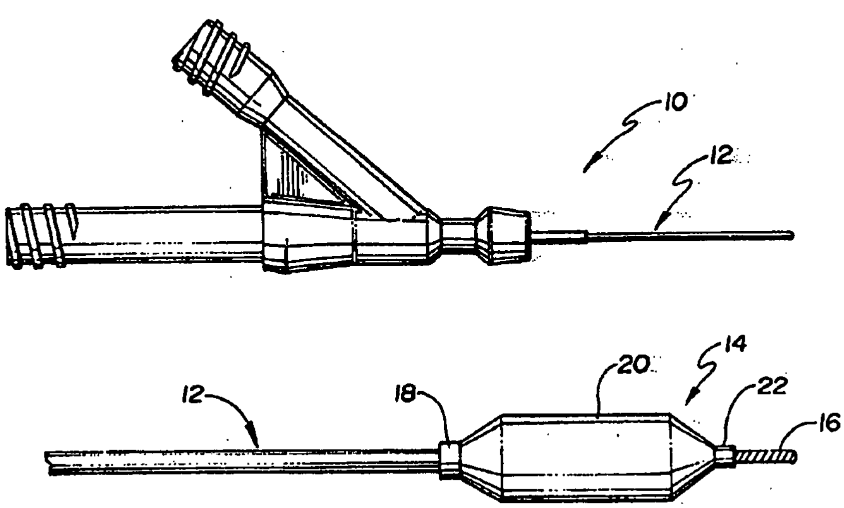
(54) Title: THERMOPLASTIC POLYIMIDE BALLOON CATHETER



(57) Abstract

The present invention discloses the incorporation of thermoplastic polyimide into various parts of balloon catheters such as catheter shafts and balloons. Such catheter construction may be integral or unitary in which the shaft or a portion thereof and balloon are manufactured as a single unit or the construction may be comprised of a separate shaft to which a balloon is attached, as by adhesive or other bonding.

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INTERNATIONAL SEARCH REPORT

Inten nal Application No
PCT/US 94/14970

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 C08G73/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M C08G B29B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE,A,40 25 346 (BAYER AG) 13 February 1992 see page 10, line 1 - line 20; figure 1 see page 4, line 10 - line 13	1-3,18, 22
Y	see page 10, line 1 - line 10; figure 1 ---	4-17, 19-21, 23-31
Y	WO,A,93 20881 (SCIMED LIFE SYSTEMS, INC) 28 October 1993 see the whole document ---	6,10-12, 24-31
Y	EP,A,0 380 102 (ADVANCED CARDIOVASCULAR SYSTEM, INC.) 1 August 1990 see page 4, line 43 - page 5, line 20; figures 1-3 --- -/--	4,5,7-9, 13-17, 19-21,23

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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1

Date of the actual completion of the international search	Date of mailing of the international search report
9 June 1995	05.07.95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ehrsam, F

INTERNATIONAL SEARCH REPORT

Inte[illegible]nal Application No
PCT/US 94/14970

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,4 954 610 (CHEN, SR. ET AL.) 4 September 1990 see column 14, line 26 ---	23
A	EP,A,0 541 055 (CHISSO CORPORATION) 12 May 1993 see abstract ---	1,22
A	EP,A,0 391 633 (MIT) 10 October 1990 see the whole document ---	1
A	CLAIR, T.L.; BURKS, H.D. 'thermoplastic/melt-processable polyimides' 1984 , UNIVERSITÄTBIBLIOTHEK , HANNOVER cited in the application see page 337 - page 355 -----	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 94/14970

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
DE-A-4025346	13-02-92	CA-A-	2048595	11-02-92
		DE-D-	59104754	06-04-95
		EP-A-	0470464	12-02-92
		ES-T-	2069787	16-05-95
		JP-A-	4253730	09-09-92
WO-A-9320881	28-10-93	US-A-	5338295	16-08-94
		CA-A-	2117807	28-10-93
		EP-A-	0634943	25-01-95
EP-A-380102	01-08-90	CA-A-	2007743	26-07-90
		JP-A-	2289264	29-11-90
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		EP-A-	0385305	05-09-90
		JP-A-	2269741	05-11-90
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		US-A-	5290497	01-03-94
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		DE-D-	69014957	26-01-95
		DE-T-	69014957	24-05-95
		JP-A-	3042224	22-02-91
		KR-B-	9403165	15-04-94
		US-A-	5069848	03-12-91
		US-A-	5206339	27-04-93

MatWeb.com, The Online Materials Database

Overview - Polyimide

Subcategory: Polyimide; Polymer; Thermoplastic

Close Analogs:
Click button for specific proprietary grades that belong to this Overview class.

Proprietary Grades

Please be aware that some proprietary polymers may not be listed because they fall into more than one class o because of ambiguity in manufacturer's information.

Key Words: Plastics, Polymers

The property data has been taken from proprietary materials in the MatWeb database. Each property value reported is the average of appropriate MatWeb entries and the comments report the maximum, minimum, and number of data points used to calculate the value. The values are not necessarily typical of any specific grade, especially less common values and those that can be most affected by additives or processing methods.

Physical Properties	**Metric**	**English**	**Commer**
Density	1.34 - 1.43 g/cc	0.0484 - 0.0517 lb/in³	Averag 1.4 g/ Gra Count :
Water Absorption	0.24 - 0.4 %	0.24 - 0.4 %	Averag 0.31 Gra Count :
Moisture Absorption at Equilibrium	1.2 - 1.3 %	1.2 - 1.3 %	Averag 1.2 Gra Count :
Mechanical Properties			
Hardness, Rockwell E	50 - 99	50 - 99	Averag 74 Gra Count :
Hardness, Rockwell M	110	110	Gra Count :
Tensile Strength, Ultimate	72.4 - 120 MPa	10500 - 17400 psi	Averag 94.2 MI Gra Count :
Tensile Strength, Yield	120 MPa	17400 psi	Gra Count :
Elongation at Break	4 - 10 %	4 - 10 %	Averag 7.2

			Gra Count :
Tensile Modulus	1.3 - 4 GPa	189 - 580 ksi	Averag 2.5 GI Gra Count :
Flexural Modulus	2.482 - 4.1 GPa	360 - 595 ksi	Averag 3.2 GI Gra Count :
Flexural Yield Strength	82.7 - 200 MPa	12000 - 29000 psi	Averag 130 MI Gra Count :
Compressive Yield Strength	112.4 - 200 MPa	16300 - 29000 psi	Averag 150 MI Gra Count
Compressive Modulus	2.413 - 3.1 GPa	350 - 450 ksi	Averag 2.6 GI Gra Count
Poisson's Ratio	0.41	0.41	Gra Count :
Fatigue Strength	44.8 MPa	6500 psi	Gra Count :
Shear Strength	89.6 MPa	13000 psi	Gra Count :
Izod Impact, Notched	0.4 - 0.75 J/cm	0.749 - 1.41 ft-lb/in	Averag 0.53 J/c Gra Count :
Izod Impact, Unnotched	7.5 J/cm	14.1 ft-lb/in	Gra Count :
Coefficient of Friction	0.29	0.29	Gra Count
K (wear) Factor	50	50	Gra Count :
Limiting Pressure Velocity	0.35 MPa-m/sec	9990 psi-ft/min	Gra Count :

Electrical Properties

Electrical Resistivity	5e+014 - 1e+016 ohm-cm	5e+014 - 1e+016 ohm-cm	Averag 3E+ ohm-c Gra Count :
Surface Resistance	5e+015 ohm	5e+015 ohm	Gra Count :
Dielectric Constant	3.4 - 3.55	3.4 - 3.55	Averag 3.5; Gra Count :

Dielectric Constant, Low Frequency	3.4 - 3.62	3.4 - 3.62	Averag 3.5; Gra Count
Dielectric Strength	22 - 27.6 kV/mm	559 - 701 kV/in	Averag 2 kV/m Gra Count
Dissipation Factor	0.0034 - 0.005	0.0034 - 0.005	Averag 0.00 Gra Count
Dissipation Factor, Low Frequency	0.0018 - 0.005	0.0018 - 0.005	Averag 0.00 Gra Count

Thermal Properties

CTE, linear 20°C	45 - 90 µm/m-°C	25 - 50 µin/in-°F	Averag 61.3 µm/ °C; Gra Count
CTE, linear 100°C	50 - 54 µm/m-°C	27.8 - 30 µin/in-°F	Averag 52 µm/r C; Gra Count
Heat Capacity	1.13 - 1.2 J/g-°C	0.27 - 0.287 BTU/lb-°F	Averag 1.2 J/g Gra Count
Thermal Conductivity	0.1 - 0.35 W/m-K	0.694 - 2.43 BTU-in/hr-ft²-°F	Averag 0.25 W/ K; Gra Count
Maximum Service Temperature, Air	304 - 360 °C	579 - 680 °F	Averag 340 Gra Count
Deflection Temperature at 1.8 MPa (264 psi)	280 - 360 °C	536 - 680 °F	Averag 340 Gra Count
Glass Temperature	323 - 340 °C	613 - 644 °F	Averag 330 Gra Count
Flammability, UL94	V-0	V-0	Gra Count
Oxygen Index	53 %	53 %	Gra Count

Processing Properties

Processing Temperature	320 °C	608 °F	Gra

Count :

MatWeb.com, The Online Materials Database

Overview - Polyethylene Terephthalate (PET), Unreinforced

Subcategory: Polyester, TP; Polyethylene Terephthalate (PET); Polymer; Thermoplastic

Close Analogs:
Click button for specific proprietary grades that belong to this Overview class.

Proprietary Grades

Please be aware that some proprietary polymers may not be listed because they fall into more than one class or because of ambiguity in manufacturer's information.

Key Words: Polyester; Plastics, Polymers

The property data has been taken from proprietary materials in the MatWeb database. Each property value reported is the average of appropriate MatWeb entries and the comments report the maximum, minimum, and number of data points used to calculate the value. The values are not necessarily typical of any specific grade, especially less common values and those that can be most affected by additives or processing methods.

Physical Properties	**Metric**	**English**	**Comments**
Density	1.3 - 1.33 g/cc	0.047 - 0.048 lb/in³	Average = 1.32 g/cc; Grade Count = 4
Water Absorption	0.15 %	0.15 %	Grade Count = 1
Linear Mold Shrinkage	0.006 cm/cm	0.006 in/in	Grade Count = 1
Mechanical Properties			
Hardness, Rockwell M	95	95	Grade Count = 1
Hardness, Rockwell R	110	110	Grade Count = 1
Tensile Strength, Ultimate	55 MPa	7980 psi	Grade Count = 1
Tensile Strength, Yield	50 - 57 MPa	7250 - 8270 psi	Average = 54.5 MPa; Grade Count = 4
Elongation at Break	50 - 350 %	50 - 350 %	Average = 130%; Grade Count = 4
Elongation at Yield	3.8 %	3.8 %	Grade Count = 3
Tensile Modulus	2.47 - 3 GPa	358 - 435 ksi	Average = 2.7 GPa; Grade Count = 4
Flexural Modulus	1 GPa	145 ksi	Grade Count = 1
Flexural Yield Strength	80 MPa	11600 psi	Grade Count = 1
Compressive Yield Strength	90 MPa	13100 psi	Grade Count=1
Izod Impact, Notched	1.4 J/cm	2.62 ft-lb/in	Grade Count = 1
Charpy Impact, Unnotched	NB	NB	Grade Count = 3
Charpy Impact, Notched Low Temp	0.27 - 0.31 J/cm²	1.28 - 1.48 ft-lb/in²	Average = 0.29 J/cm²; Grade Count =

			3
Charpy Impact, Unnotched Low Temp	NB	NB	Grade Count = 3
Charpy Impact, Notched	0.38 - 0.49 J/cm²	1.81 - 2.33 ft-lb/in²	Average = 0.42 J/cm²; Grade Count = 3

Electrical Properties

Electrical Resistivity	2e+015 ohm-cm	2e+015 ohm-cm	Grade Count = 1
Dielectric Constant	3	3	Grade Count = 1
Dielectric Strength	18 kV/mm	457 kV/in	Grade Count = 1
Dissipation Factor	0.02	0.02	Grade Count = 1

Thermal Properties

CTE, linear 20°C	73 - 92 µm/m-°C	40.6 - 51.1 µin/in-°F	Average = 79.2 µm/m-°C; Grade Count=4
CTE, linear 20°C Transverse to Flow	48 - 78 µm/m-°C	26.7 - 43.3 µin/in-°F	Average = 61.7 µm/m-°C; Grade Count=3
Thermal Conductivity	0.2 W/m-K	1.39 BTU-in/hr-ft²-°F	Grade Count = 1
Melting Point	243 - 250 °C	469 - 482 °F	Average = 250°C; Grade Count = 4
Maximum Service Temperature, Air	63 - 100 °C	145 - 212 °F	Average = 74°C; Grade Count = 4
Deflection Temperature at 0.46 MPa (66 psi)	68 - 72 °C	154 - 162 °F	Average = 69.7°C; Grade Count=3
Deflection Temperature at 1.8 MPa (264 psi)	63 - 100 °C	145 - 212 °F	Average = 74°C; Grade Count=4
Vicat Softening Point	74 - 76 °C	165 - 169 °F	Average = 75.3°C; Grade Count = 3
Glass Temperature	73 - 78 °C	163 - 172 °F	Average = 76.5°C; Grade Count = 4

Processing Properties

Processing Temperature	280 - 300 °C	536 - 572 °F	Average = 290°C; Grade Count = 4

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Accessories
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Rockwell Scales (Complete listing)

Scale Name	Indenter	Major Load	Minor Load	Applications*
Regular Rockwell Scales				
A	Diamond	60 kg	10 kg	Cemented carbides, thin steel and shallow case hardene
B	1/16" ball	100 kg	10 kg	Copper alloys, soft steels, aluminum alloys, mealleable
C	Diamond	150 kg	10 kg	Steel, hard cast irons, pearlitic malleable iron, titanium, case-hardnened steel and the materials harder than HF
D	Diamond	60 kg	10 kg	Thin steel and medium case-hardnened steel and pea malleable iron
E	1/8" ball	100 kg	10 kg	Cast iron, aluminum and magnesium alloys, bearing m
F	1/16" ball	60 kg	10 kg	Annealed copper aloovs, thin soft wheet metals.
G	1/16" ball	150 kg	10 kg	Phosphor bronze, beryllium copper, malleabel irons. U limit is HRG 92 to avoid possible flattening of the ba
H	1/8" ball	100 kg	10 kg	Aluminum, Zinc, Lead
K	1/8" ball	150 kg	10 kg	Bearing metals and otehr very soft or thin materials. samllest ball and heaviest load that do not give and anvi
L	1/4" ball	60 kg	10 kg	[Same as K]
M	1/4" ball	100 kg	10 kg	[Same as K]
P	1/4" ball	150 kg	10 kg	[Same as K]
R	1/2" ball	60 kg	10 kg	[Same as K]
S	1/2" ball	100 kg	10 kg	[Same as K]
V	1/2" ball	150 kg	10 kg	[Same as K]
Superficial Rockwell Scales				
15N	Diamond	15 kg	3 kg	Similar to C scale, but for thin materials
30N	Diamond	30 kg	3 kg	[Same as 15N]
45N	Diamond	45 kg	3 kg	[Same as 15N]
15T	1/16" ball	15 kg	3 kg	Similar to B scale, but for thin materials
30T	1/16" ball	30 kg	3 kg	[Same as 15T]
45T	1/16" ball	45 kg	3 kg	[Same as 15T]
15W	1/8" ball	15 kg	3 kg	Used for very soft materials
30W	1/8" ball	30 kg	3 kg	Used for very soft materials
45W	1/8" ball	45 kg	3 kg	Used for very soft materials
15X	1/4" ball	15 kg	3 kg	Used for very soft materials
30X	1/4" ball	30 kg	3 kg	Used for very soft materials
45X	1/4" ball	45 kg	3 kg	Used for very soft materials
15Y	1/2" ball	15 kg	3 kg	Used for very soft materials
30Y	1/2" ball	30 kg	3 kg	Used for very soft materials
45Y	1/2" ball	45 kg	3 kg	Used for very soft materials

*** Permission to reprint application information in Regular Rockwell scale from: *Hardness Testing* (1987) ASM International, Materials Park, OH, 44073-0002, table 2, p 46.**

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Hardness Measurement and Specifications:

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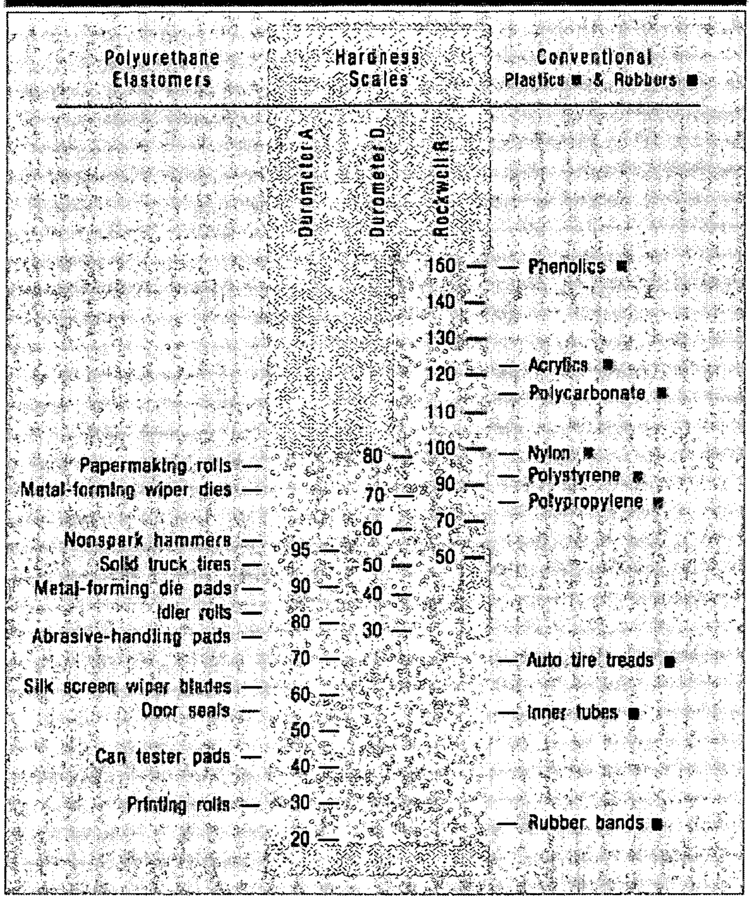
SHORE Hardness: Note, on the table below Durometer A and Durometer D is the same as Shore A and Shore D.

Figure 1 *Hardness*



The shore scleroscope measures hardness in terms of the elasticity of the material. A diamond-tipped hammer in a graduated glass tube is allowed to fall from a known height on the specimen to be tested, and the hardness number depends on the height to which the hammer rebounds; the harder the material, the higher the rebound.

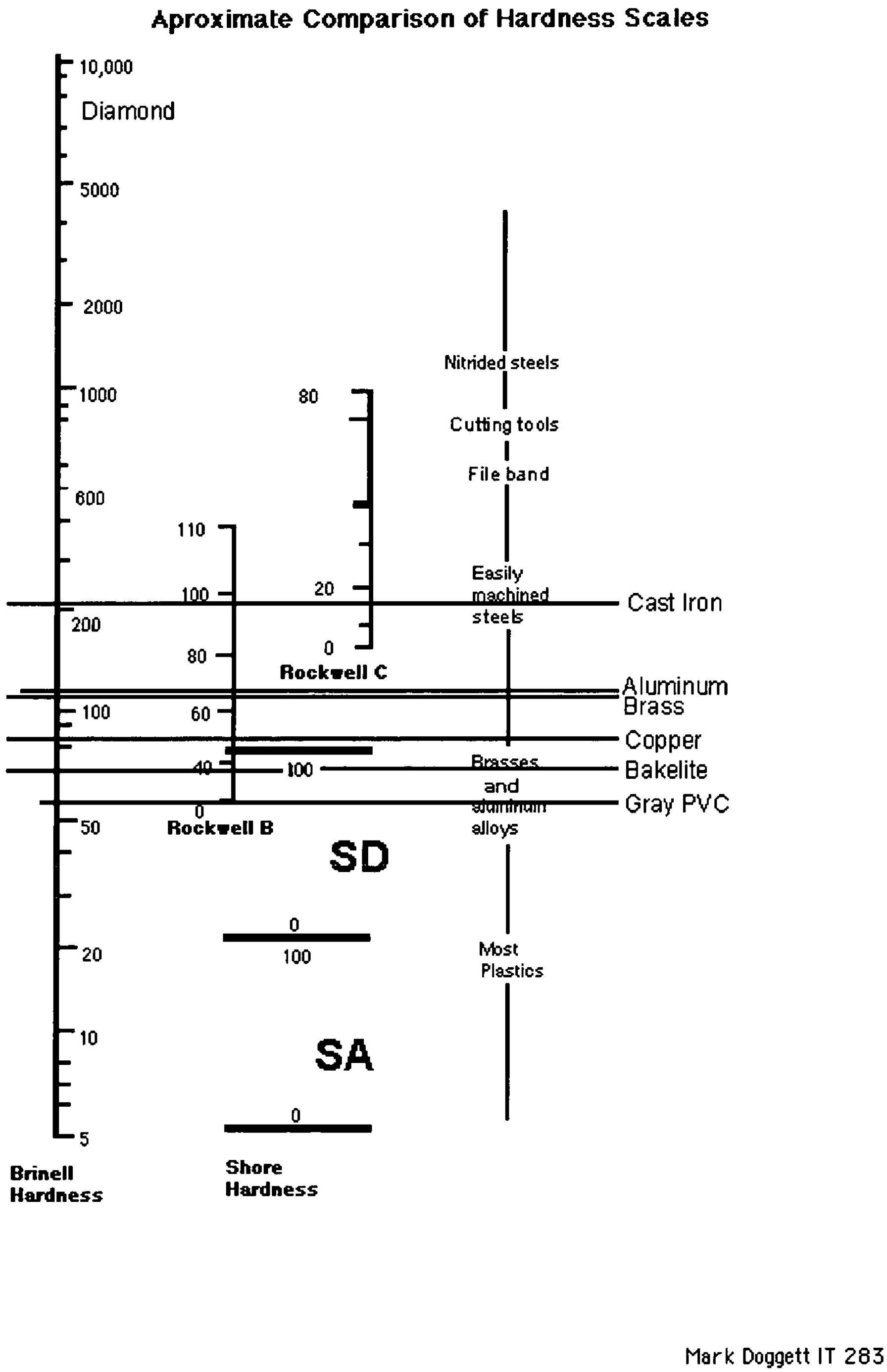
Shore hardness is a measure of the resistance of material to indentation by 3 spring-loaded indenter. The higher the number, the greater the resistance.

The hardness testing of plastics is most commonly measured by the Shore (Durometer) test or Rockwell hardness test. Both methods measure the resistance of the plastic toward indentation. Both scales provide an empirical hardness value that doesn't correlate to other properties or fundamental characteristics. Shore Hardness, using either the Shore A or Shore D scale, is the preferred method for rubbers/elastomers and is also commonly used for 'softer' plastics such as polyolefins, fluoropolymers, and vinyls. The Shore A scale is used for 'softer' rubbers while the Shore D scale is used for 'harder' ones. The shore A Hardness is the relative hardness of elastic materials such as rubber or soft plastics

can be determined with an instrument called a Shore A durometer. If the indenter completely penetrates the sample, a reading of 0 is obtained, and if no penetration occurs, a reading of 100 results. The reading is dimensionless.

The Shore hardness is measured with an apparatus known as a Durometer and consequently is also known as 'Durometer hardness'. The hardness value is determined by the penetration of the Durometer indenter foot into the sample. Because of the resilience of rubbers and plastics, the hardness reading my change over time - so the indentation time is sometimes reported along with the hardness number. The ASTM test number is ASTM D2240 while the analogous ISO test method is ISO 868.

The results obtained from this test are a useful measure of relative resistance to indentation of various grades of polymers. However, the Shore Durometer hardness test does not serve well as a predictor of other properties such as strength or resistance to scratches, abrasion, or wear, and should not be used alone for product design specifications.


Aproximate Comparison of Hardness Scales
10,000
Diamond
5000
2000
1000
600
200
100
50
20
10
5
Brinell Hardness
110
100
80
60
40
0
Rockwell B
80
20
0
Rockwell C
100
SD
0
100
SA
0
Shore Hardness
Nitrided steels
Cutting tools
File band
Easily machined steels
Cast Iron
Aluminum
Brass
Copper
Brasses and aluminum alloys
Bakelite
Gray PVC
Most Plastics
Mark Doggett IT 283

TEST	TEST METHOD	TEST FORCE RANGE	INDENTER TYPES	ASTM TEST METHOD	MEASURE METHOD
Rockwell	Regular	60, 100, 150 kgs	Conical Diamond & Small Ball	E 18	Depth
	Superficial	15, 30, 45 kgs	Conical Diamond & Small Ball	E 18	Depth
	Light Load	3, 5, 7 kgs	Truncated Cone Diamond	N/A	Depth
	Micro	500, 100 grams	Small Truncated Cone Diamond	N/A	Depth
	Macro	500 to 3000 kgs	5, 10 mm Ball	E 103	Depth
Micro-Hardness	Vickers	5 to 2000 grams	136° Pyramid Diamond	E 384	Area
	Knoop	5 to 2000 grams	1300 x 1720° Diamond	E 384	Area
	Rockwell Type	500, 3000 grams	Truncated Cone Diamond	N/A	Depth
	Dynamic	.01 to 200 grams	Triangular Diamond	N/A	Depth
Brinell	Optical	500 to 3000 kgs	5mm, 10 mm Ball	E 10	Area
	Depth	500 to 3000 kgs	5mm, 10 mm Ball	E 103	Depth
Shore	Regular	822 (A), 4560 (D) grams	35° Cone (A) 30° Cone (D)	D 2240	Depth
	Micro	257 (A), 1136 (D) grams	35° Cone (A) 30° Cone (D)	N/A	Depth
IRHD	Regular	597 grams	2.5 mm Ball	D 1415	Depth
	Micro	15.7 grams	.395 mm Ball	D 1415	Depth

For more detailed information on hardness please go to:

Images and text gleaned from CALCE University of Maryland.

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